

Remarks

The foregoing amendments are believed to place the claims in condition for allowance or in better condition for consideration on appeal. 37 C.F.R. § 1.116(a). Accordingly, their entry after final rejection is respectfully requested.

1. Status of the Claims

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 146-148, 150-174, 176, 177, 180-203, 233, and 237-244 are pending in the application, with claims 146-148, 176, 177, and 233 being the independent claims. Claims 175 and 179 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein.

Claims 146-148, 176, 177, and 233 have been amended by replacing "kiwifruit of the genus Actinidia" with "Actinidia arguta." Support for these amendments can be found in the specification at page 6, lines 31-32. Claims 146-148, 176, and 177 have also been amended by replacing "atopic dermatitis" with "allergic disease." Claim 233 has also been amended by deleting the phrase "wherein said allergic disease is atopic dermatitis." Support for these amendments can be found in the specification at page 4, lines 3-31. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendments and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

II. The Rejections

A. Rejection #1 Under 35 U.S.C. § 103(a)

Claims 146-148, 150-153, 155-177, 179-183, 185-203, 233, and 237-244 are rejected under 35 U.S.C. § 103(a), as allegedly being obvious over Murad (U.S. Pat. No. 6,630,163) in view of Endres *et al.* (DE 19758090 A1) and/or Udagawa (JP 61140510 A) and/or Luo *et al.* (CN 1107308 A), Tsuboi *et al.* (JP 02202808 A), Wuthrich (*Clin. Exp. Allergy* 8(3):241-248), Lukacs *et al.* (U.S. Pat. Appl. No. 2002/0006410 A1), and Capetola *et al.* (U.S. Pat. No. 4,444,780). Applicants respectfully traverse the rejection.

1. Elements of a Prima Facie Case of Obviousness

In order to establish a *prima facie* case of obviousness, (1) there must be some reason, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP § 2143.

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007) (*KSR*), noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. Quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), the Court stated that "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR v. Teleflex*, 550 U.S. at 735, 82 USPQ2d at 1396. As outlined in MPEP § 2141, rationales that may support a conclusion of obviousness include:

(a) combining prior art elements according to known methods to yield predictable results;

(b) simple substitution of one known element for another to obtain predictable results;

(c) use of known technique to improve similar devices (method or product) ready for improvement to yield predictable results;

(d) applying a known technique to a known device (method or product) ready for improvement to yield predictable results;

(e) "obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(f) known work in the one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;

(g) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Applicants respectfully submit that the Examiner has not provided an adequate reason to combine the reference teachings to arrive at Applicants' claimed invention, *i.e.*, methods of treating, alleviating or reducing one or more symptoms of *allergic disease* via the *oral* administration of an extract of *Actinidia arguta*. At best, the combination of cited references is an invitation to experiment. Furthermore, Applicants respectfully submit that even if the cited references are combined, they do not teach each and every claimed limitation. Thus, the Examiner has not established a *prima facie* case of

obviousness and Applicants respectfully request that the rejections be reconsidered and withdrawn.

2. Murad (U.S. Pat. No. 6,630,163)

As discussed in Applicants' Amendment and Reply dated October 15, 2009, Murad merely mentions the use of fruit extracts to treat a multitude of inflammatory dermatological conditions listed at col. 8, lines 2-12, and mentions kiwi in a laundry list of fruits. Murad contains only one working example in which a fruit extract is used for any therapeutic or preventive purpose: treating sun-exposed skin. Murad does not disclose methods of treating, alleviating or reducing one or more symptoms of *allergic disease* via the *oral* administration of an *Actinidia arguta* extract.

At page 4 of the Office Action dated January 6, 2010, the Examiner admits that "Murad does not explicitly teach the claimed species of kiwi fruit nor the extraction process." Applicants submit that they are in agreement with the Examiner's admission. As such, the reference does not teach all of the claim limitations of the pending claims.

3. Endres et al. (DE 19758090 A1)

While Endres mentions using *Actinidia arguta* extracts to *topically* treat *non-allergic* inflammatory dermatological conditions, Endres does not disclose the *oral* treatment of any *allergic* condition with *Actinidia arguta* extracts. Applicants submit that there is no reason, either in Endres or in the knowledge generally available to one of ordinary skill in the art, to modify Endres or to combine the teachings of Murad and Endres to arrive at the claimed invention, *i.e.*, *orally* treating, alleviating or reducing one or more symptoms of *allergic disease* in a mammal in need thereof with an *Actinidia arguta* extract. Additionally, the combination of Murad and Endres fails to provide a

reasonable expectation for successfully treating, alleviating or reducing one or more symptoms of allergic disease by orally administering an *Actinidia arguta* extract to a mammal in need thereof.

At page 10 of the Office Action, the Examiner asserts that "Endres teaches the hardy kiwi juice is used in treating psoriasis an allergic inflammatory disease (also see Pegg et al. US 5955463 A col 11 lines 20-25)." It appears that the Examiner is relying on U.S. Pat. No. 5,955,463 ("Pegg") to categorize psoriasis as an allergic disease. Pegg was filed on March 9, 1993. Applicants submit that Pegg does not teach the molecular mechanism underlying psoriasis. Nor does Pegg provide peer-reviewed, scientific references to support the assertion that psoriasis is an allergic disease. Rather, the single sentence in Pegg that the Examiner relies on to support her assertion is a bogus teaching provided by an outdated reference.

In the event that the teachings of two or more prior art references conflict, the M.P.E.P. §2143.01 (Eighth Edition, Rev. August 2007) states that

[t]he test for obviousness is what the **combined** teachings of the references would have suggested to one of ordinary skill in the art, Where the teachings of two or more prior art references **conflict**, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another. *In re Young*, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991)

Id. (emphasis added).

Applicants submitted numerous peer-reviewed, scientific references detailing the underlying mechanism of psoriasis, a non-allergic disease, and distinguishing it from atopic dermatitis, an allergic disease, in their Amendment and Reply dated April 6, 2009, including Nomura, I. *et al.*, *J. Immunol.* 171:3262-3269 (2002), Traub, M. and Marshall,

K. *Alt. Med. Rev.* 12:319-330 (2007), Broide, D. and Sriramaraio, P., *Immunol. Rev.* 179:163-172 (2002), and Leung, D.Y., *Clin. Exp. Immunol.* 107 Suppl 1:25-30 (1997). Applicants now submit Ghoreschi, K. and Rocken, M., *Curr. Drug Targets Inflamm. Allergy* 3(2):193-198 (2004), which discusses the use of IL-4, a T_H2 cytokine, to treat psoriasis and Koreck, A. *et al.*, *Clin. Exp. Immunol.* 127(1):176-182 (2002), which discusses the primary involvement of T_H1 related cytokines in psoriasis (Exhibits A and B, respectively). The combined teachings of these references would have suggested to a person of ordinary skill in the art at the time the application was filed that the molecular mechanisms underlying psoriasis and allergic disease are different and that a subject with psoriasis would not benefit from a reduction in T_H2 serum cytokines or an increase in T_H1 serum cytokines, as recited in the pending claims.

Additionally, the volume of peer-reviewed, scientific references supplied by the Applicants regarding the mechanism and categorization of psoriasis outweighs the unsupported and outdated single sentence teaching relied upon by the Examiner. Thus, the combined teachings of these references would have suggested to a person of ordinary skill in the art at the time the application was filed that psoriasis is not an allergic disease and that Endres does not teach treating, alleviating or reducing one or more symptoms of allergic disease.

4. *Udagawa (JP 61140510 A)*

While Udagawa mentions the use of *Actinidia kolomikta* and *Actinidia polygama* fruit extracts in *cosmetics* and juices as a starting material in food, Udagawa also does not teach *orally* administering *Actinidia arguta* extracts to treat, alleviate or reduce one or more symptoms of *allergic disease* in a mammal in need thereof.

Again, there is no reason, either in Udagawa or in the knowledge generally available to one of ordinary skill in the art, to modify Udagawa or to combine reference teachings to arrive at methods for orally treating, alleviating or reducing one or more symptoms of allergic disease with *Actinidia arguta* extracts simply by combining the Murad, Endres and Udagawa references. Additionally, the combined references fail to provide a reasonable expectation for successfully treating, alleviating or reducing one or more symptoms of allergic disease by orally administering an *Actinidia arguta* extract to a mammal in need thereof.

5. *Luo et al. (CN 1107308 A)*

Luo generally discusses the use of kiwi fruit extracts and beverages for the treatment of illness, but does not specifically mention *Actinidia arguta* extracts or the treatment, alleviation or reduction of one or more symptoms of allergic disease. Like Murad, Endres and Udagawa, Luo does not explicitly teach treating, alleviating or reducing one or more symptoms of ***allergic disease*** by ***orally*** administering an *Actinidia arguta* extract to a mammal in need thereof. As such, the references combined fail to provide a reasonable expectation for successfully treating, alleviating or reducing one or more symptoms of allergic disease.

6. *Tsuboi et al. (JP 02202808 A); Wuthrich (Clin. & Exp. Allergy 8:241-248); Lukacs et al. (U.S. Pat. Appl. Publ. No. 2002/0006410); and Capetola et al. (U.S. Pat. No. 4,444,780 A)*

The Examiner has additionally cited Tsuboi, Wuthrich, Lukacs and Capetola. Tsuboi discusses kiwifruit extract compositions generally, but does not specifically mention *Actinidia arguta* extracts or the treatment, alleviation or reduction of one or more symptoms of allergic disease. Wuthrich describes increased IgE production

associated with atopic dermatitis. Lukacs discusses what is already known in the art by way of T_H1/T_H2 immune response mechanisms. Capetola describes a relationship between histamine release and edema and atopic dermatitis. Applicants submit that none of the cited references disclose **orally** treating, alleviating or reducing one or more symptoms of **allergic disease** with extracts of *Actinidia arguta* as recited in independent claims 146-148, 176, 177, and 233. Therefore, none of these references cure the deficiencies of Murad, Endres, Udagawa, and Luo.

7. **Summary**

The Examiner asserts that the combination of the Murad, Endres, Udagawa, Luo, Tsuboi, Wuthrich, Lukacs and Capetola references renders the invention obvious. As explained above, the claimed methods are non-obvious because the cited references (1) do not teach (individually or in combination) the treatment, alleviation or reduction of one or more symptoms of **allergic disease** by **orally** administering *Actinidia arguta* extracts to a mammal in need thereof; (2) do not provide one of skill in the art with a reason to modify the references to arrive at the claimed invention; and (3) do not provide a reasonable expectation of success. As such, Applicants submit that with regard to the pending claims the Examiner has failed to make a *prima facie* case of obviousness.

Accordingly, it is respectfully requested that the rejection of pending claims 146-148, 150-153, 155-174, 176, 177, 180-183, 185-203, 233, and 237-244 under 35 U.S.C. § 103, as allegedly being obvious, be reconsidered and withdrawn.

8. ***The Evidence of Superior Results of Presently Claimed Methods Rebuts Any Prima Facie Case of Obviousness***

Even assuming, *arguendo*, that a *prima facie* case of obviousness has been established, which it has not, the unexpected superior results achieved using *Actinidia*

arguta extracts over Murad's commercial kiwifruit extracts for the oral treatment, alleviation or reduction of one or more symptoms of allergic disease, is sufficient to rebut the *prima facie* case of obviousness.

Applicants submit that even assuming, *arguendo*, that the combination of references cited by the Examiner rendered the claimed invention obvious, one of ordinary skill in the art would expect to observe similar results between *Actinidia arguta* extracts and commercial kiwifruit (*Actinidia deliciosa*) extracts when administered orally to treat, alleviate or reduce one or more symptoms of allergic disease, *i.e.*, similar reductions in serum IgE and T_H1 cytokines, and not the superior results the Applicants have observed.

a. *Actinidia Extract Preparation*

Applicants purchased *Actinidia arguta* and *Actinidia deliciosa* fruits from a farm specializing in the cultivation of *Actinidia arguta* (Hurstberry, Oregon, USA) and a supermarket, respectively. After air-drying, it was determined that the fruits had a moisture content of <10%. The dried fruit (10g) was extracted three times by heat treatment in distilled water (DW) to yield a water-soluble extract. The water-soluble extract was filtered (No. 2 Filter Paper; 110 mm, Whatman), concentrated using a rotary evaporator, and freeze-dried. Freeze-dried extracts were then dissolved in DW at a concentration of 100 mg/mL and stored at -80 °C until they were ready for use.

b. *U266B1 Cell Preparation and Use*

U266B1 cells (human B cell line useful for studying allergic responses *in vitro*) were cultured in 24 well plates (2×10⁵ cells/well) in RPMI-1640 medium supplemented with 10 % FBS, 2 mM L-glutamine, 10 mM HEPES, 1 mM sodium pyruvate, 50 µg

streptomycin, and 100 U/ml penicillin (all from Life Technologies) at 37 °C under 5% CO₂. Cells were treated with an allergen, lipopolysaccharide ("LPS") (2 µg/ml), and *Actinidia arguta* or *Actinidia deliciosa* extracts (500 µg/ml). After 7 days of culture, the cell supernatants were collected to measure the level of IgE in the supernatants by ELISA (total human IgE; AlerChek). The results were expressed as a percentage of inhibitory activity on LPS-mediated IgE production.

c. Results

As shown in Exhibit C, the extract of *Actinidia arguta* decreased the LPS-mediated production of IgE by 70%, while the extract from *Actinidia deliciosa* inhibited IgE production by only 37%. The difference between the levels of IgE inhibition by extracts of *Actinidia arguta* and *Actinidia deliciosa* is statistically significant. These results demonstrate that *Actinidia arguta* extracts are approximately 2-fold more potent than *Actinidia deliciosa* extracts at inhibiting IgE production. Applicants submit that the combined teachings of the cited references fail to demonstrate the unexpected superior potency of *Actinidia arguta* extracts to inhibit IgE production. Accordingly, these results are sufficient to rebut the *prima facie* case of obviousness

d. Splenocyte Preparation and Use

BALB/c female mice (7 weeks old) were individually immunized and later boosted by intraperitoneal (i.p.) injections of 20 µg of ovalbumin "(OVA)" (grade V; Sigma) emulsified in 2.25 mg of aluminum hydroxide (ImjectAlum; Pierce) on day 0 and day 14, respectively. Non-sensitized (naive) mice did not receive any reagent. On day 24, both OVA-sensitized and naive mice were sacrificed (n=5/group), and the spleens of these animals were isolated to study the production of cytokines in splenocytes using the

recall response. Briefly, spleens in each group of mice were obtained, pooled and homogenized under sterile conditions. Splenocytes were filtered through a 60 μm pore nylon sieve to remove large aggregates, washed with HEPES-buffered RPMI-1640 medium, and centrifuged at 1500 rpm for 5 min. After centrifugation, the supernatant was discarded, and the splenocytes were resuspended in culture medium (RPMI-1640 containing 10% heat-inactivated FBS). The resulting splenocyte suspension was seeded into a 24 well culture plate, while adjusting the final concentration of splenocytes to 5×10^6 cells/ml/well. Splenocytes were incubated with 100 $\mu\text{g/ml}$ of OVA in the presence of *Actinidia arguta* or *Actinidia deliciosa* extract (1 mg/ml, respectively), or media as a control for 3 days. Following incubation, the splenocyte culture supernatants were collected to detect the level of IL-4 and IL-5 using respective ELISA kits (Endogen).

e. Results

As shown in Exhibit D, the extract of *Actinidia arguta* significantly decreased the OVA-stimulated production of IL-4 by 70%, while the extract of *Actinidia deliciosa* inhibited IL-4 production by only 29%. The difference between the levels of IL-4 production by extracts of *Actinidia arguta* and *Actinidia deliciosa* is statistically significant. These results demonstrate that *Actinidia arguta* extracts are about 2.5-fold more potent than *Actinidia deliciosa* extracts at inhibiting IL-4 production. Applicants submit that the combined teachings of the cited references fail to demonstrate the unexpected superior potency of *Actinidia arguta* extracts to inhibit IL-4 production. Accordingly, these results are sufficient to rebut the *prima facie* case of obviousness

B. Rejection #2 Under 35 U.S.C. § 103(a)

Claims 154 and 184 are rejected under 35 U.S.C. § 103(a), as allegedly being obvious over Murad in view of Endres and/or Udagawa and/or Luo, Tsuboi, Wuthrich, Lukacs, and Capetola, and further in view of Suzuki *et al.* (U.S. Publ. No. 2002/0054923 A1). Applicants respectfully traverse the rejection.

Pending claim 154 depends from claim 151, which in turn depends from independent claims 146-148. Accordingly, claim 154 incorporates the limitations of claims 146-148 and 151. Pending claim 184 depends from claim 181, which in turn depends from independent claims 176 and 177. Accordingly, claim 184 incorporates the limitations of claims 176, 177, and 181. As discussed above, Murad, Endres, Udagawa, and Luo do not teach each and every claim limitation of the pending claims. Additionally, none of the references teach the mechanism underlying allergic disease. Applicants submit that Tsuboi, Wuthrich, Lukacs, Capetola, and Suzuki also do not disclose orally treating, alleviating or reducing one or more symptoms of allergic disease with *Actinidia arguta* extracts as recited in independent claims 146-148, 176, and 177. Suzuki merely discusses commercial kiwifruit extract compositions. As such, Applicants submit that no reason is provided, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings to arrive at methods for *orally* treating, alleviating or reducing one or more symptoms of *allergic disease* with *Actinidia arguta* extracts simply by combining the Murad, Endres, Luo, Tsuboi, Wuthrich, Lukacs, Capetola, and Suzuki references. Moreover, a skilled person in the art would not have had a reasonable expectation of achieving the desired therapeutic results based solely on the cited

references. As such, Applicants submit that the Examiner has failed to make a *prima facie* case of obviousness.

Accordingly, it is respectfully requested that the rejection of pending claims 154 and 184 under 35 U.S.C. § 103(a), as allegedly being obvious, be reconsidered and withdrawn.

Even assuming, *arguendo*, that a *prima facie* case of obviousness had been established, which it had not, the unexpected superior results achieved using *Actinidia arguta* extracts over Murad's commercial kiwifruit extracts for the oral treatment, alleviation or reduction of one or more symptoms of allergic disease as discussed above, is sufficient to rebut the *prima facie* case of obviousness.

C. Rejections #3 Under 35 U.S.C. § 103(a)

Claims 146-148, 150-153, 155-177, 179-183, 185-203, 233, and 237-244 are rejected under 35 U.S.C. § 103(a), as allegedly being obvious over Motohashi N., *West Aust. Nut and Tree Crops Assoc.* 16:48-59 (1991), Tsuboi, Wuthrich, Lukacs, and Capetola. Applicants respectfully traverse the rejection.

1. Motohashi (West Aust. Nut and Tree Crops Assoc. 16:48-59 (1991))

Motohashi mentions that *Actinidia eriantha*, a non-hardy kiwifruit plant species, can be used to treat dermatitis, an allergic disease. However, Motohashi fails to describe which parts of the *Actinidia eriantha* plant are useful for treating dermatitis or how such treatment is administered. Additionally, Motohashi fails to describe extracts of *Actinidia eriantha*. While Motohashi also mentions that *Actinidia chinensis* and *Actinidia callosa* can be used to treat edema, neither of these kiwifruit species are hardy kiwifruit species. Thus, not only does Motohashi fail to disclose extracts of *Actinidia arguta* for the *oral*

treatment, alleviation or reduction of one or more symptoms of dermatitis, Motohashi fails to disclose extracts of any hardy kiwifruit species for the oral treatment, alleviation or reduction of one or more symptoms of any *allergic disease*. As such, the reference does not teach all of the claim limitations of any of the pending claims.

2. Tsuboi, Wuthrich, Lukacs, and Capetola

As mentioned above, Tsuboi, Wuthrich, Lukacs, and Capetola do not disclose *orally* treating, alleviating or reducing one or more symptoms of *allergic disease* with extracts of *Actinidia arguta* as recited in independent claims 146-148, 176, 177, and 233. Therefore, none of these references cure the deficiencies of Motohashi. Also as explained above, the claimed methods are non-obvious because the cited references (1) do not teach (individually or in combination) the treatment of *allergic disease* by *orally* administering *Actinidia arguta* extracts to a mammal in need thereof; (2) do not provide one of skill in the art with a reason to modify the references to arrive at the claimed invention; and (3) do not provide a reasonable expectation of success. As such, Applicants submit that with regard to the pending claims the Examiner has failed to make a *prima facie* case of obviousness.

Accordingly, it is respectfully requested that the rejection of pending claims 146-148, 150-153, 155-174, 176, 177, 180-183, 185-203, 233, and 237-244 under 35 U.S.C. § 103(a), as allegedly being obvious, be reconsidered and withdrawn.

D. Rejection #4 Under 35 U.S.C. § 103(a)

Claims 154 and 184 are rejected under 35 U.S.C. § 103(a), as allegedly being obvious over Motohashi in view of Tsuboi, Wuthrich, Lukacs, and Capetola, and further in view of Suzuki. Applicants respectfully traverse the rejection.

Pending claim 154 incorporates the limitations of claims 146-148 and 151. Pending claim 184 incorporates the limitations of claims 176, 177, and 181. As discussed above, Motohashi does not teach each and every claim limitation of the pending claims. Additionally, none of the references teach the mechanism underlying allergic disease. Applicants submit that Tsuboi, Wuthrich, Lukacs, Capetola, and Suzuki also do not disclose *orally* treating, alleviating or reducing one or more symptoms of *allergic disease* with *Actinidia arguta* extracts as recited in independent claims 146-148, 176, and 177. Suzuki merely discusses commercial kiwifruit extract compositions. As such, Applicants submit that no reason is provided, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings to arrive at methods for *orally* treating, alleviating or reducing one or more symptoms *allergic disease* with *Actinidia arguta* extracts simply by combining the Motohashi, Tsuboi, Wuthrich, Lukacs, Capetola, and Suzuki references. Moreover, a skilled person in the art would not have had a reasonable expectation of achieving the desired therapeutic results based solely on the cited references. As such, Applicants submit that the Examiner has failed to make a *prima facie* case of obviousness.

Accordingly, it is respectfully requested that the rejection of pending claims 154 and 184 under 35 U.S.C. § 103(a), as allegedly being obvious, be reconsidered and withdrawn.

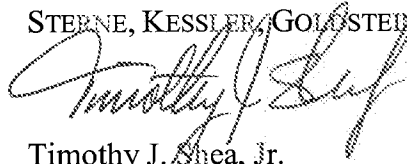
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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